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General Counsel

August 27, 2001

Dockets Management Branch (HFA-305)  
Food and Drug Administration, Rm. 1061  
5630 Fishers Lane  
Rockville, Maryland 20852

Re: Docket No. 98D-0969 – Response to the Exponent Review of Pathogen Load Studies

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments on the “Effect of the Use of Antimicrobials in Food-Producing Animals on Pathogen Load: Systematic Review of the Published Literature” prepared for the FDA Center for Veterinary Medicine by Exponent, Alexandria, Virginia.

AHI is the national trade association representing research-based manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. Our member companies produce the vast majority of all such products in the United States, as well as the world market.

### **PATHOGEN LOAD STUDIES OF NO VALUE**

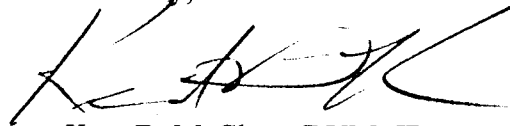
The studies cited by Exponent in the systematic literature review conducted for CVM on the effect of the use of antimicrobials in food-producing animals on pathogen load demonstrate that there is no increase in pathogen load due to administration of antimicrobials in feed. This led Exponent to conclude that antimicrobial administration presents little concern relative to pathogen load. This conclusion is in accord with that reached a year earlier by the invited participants at the Pre-Approval Studies Workshop held on February 22-24, 2000. At that meeting, the vast majority opinion was that pathogen load studies were of no value in the pre-approval process for New Animal Drugs. The breakout group addressing use of antibiotics for ruminants found that “pathogen load studies are highly variable and not predictive relative to public health concerns,” and the group addressing avian antibiotic use found “pathogen load – not relevant in pre-approval process.” The conclusions of the scientists within the breakout groups, namely that animal models of pathogen load are not predictive of a public health impact, was captured in a separate AHI Docket submission (See AHI May 3, 2000 submission to FDA Docket No. 98D-0969, “FDA Workshop on Pre-Approval Studies in Antimicrobial Resistance and Pathogen Load”).

## **FURTHER DEBATE ON PATHOGEN LOAD A WASTE OF RESOURCES**

CVM has more than sufficient information regarding the potential utility of pathogen load studies. The overwhelming input from the Pre-Approval Studies Workshop that pathogen load studies were of no value in assessing the human safety of veterinary antimicrobials should have been sufficient to end the discussion and drop them from consideration. Coupled with the literature review commissioned by CVM, there is more than sufficient information to support abandoning the concept of pathogen load studies as a condition of approval. We have learned that CVM is now contemplating referring the issue of the potential utility of pathogen load studies to the Veterinary Medicine Advisory Committee (VMAC) in January 2002. Such would be a tremendous waste of valuable time and money, and does nothing to further the review and development of antibiotic policy within CVM.

The Center has failed to move forward on resistance policy for more than two years, casting their net for support of preconceived problems and solutions, while ignoring the weight of the evidence. The handling of pathogen load studies is merely an illustrative example. CVM should follow the overwhelming information in hand and drop pathogen load studies from consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kent D. McClure', with a stylized flourish at the end.

Kent D. McClure, DVM, JD